

Forward to: DCC - HFM-99, Woodmont I - 200N

## CBER DOCUMENT CONTROL FILE SHEET

### REGULATORY MATERIALS - BLA RELATED

#### Instructions:

Fill out this form completely. Firmly attach this form to any documents to be submitted to the DCC for filing.  
Send this form with attached documents to the Document Control Center, HFM-99.  
Do not use this form when returning documents to the DCC for reshelving.  
Questions? Call us at the DCC. Phone 827-5940.

#### Document Type/Description

<input type="checkbox"/> Biologic License Material	<input type="checkbox"/> Unlicensed Establishment Correspondence
<input type="checkbox"/> Adverse Event Report	
<input type="checkbox"/> Product Promotional Material	
<input type="checkbox"/> Establishment Inspection Report	

#### Date

--

Enter as appropriate: Approval date of application or supplement submission  
Month/year for Adverse Event, Product Promotional material  
Date of Inspection

#### File Attributes - (List Multiple Application Numbers on attached sheet)

STN - Complete both Levels		Status of Application (Check Appropriate Box) <input type="checkbox"/> Approved <input type="checkbox"/> Withdrawn <input type="checkbox"/> Revoked <input type="checkbox"/> Denied <input type="checkbox"/> Completed <input type="checkbox"/> Refusal to File	
First Level	Second Level		
License Number	<input type="checkbox"/> Multiple STN Submission (Include list of all STN on separate sheet)		
Description			

#### Submitted By:

Name	Date Submitted to DCC
Division Mail Code	Telephone Number

For DCC Use Only:  
Verified By:

Filed By: